IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8497

Bartle, C.J. June 30, 2010

Marti Chizar ("Ms. Chizar" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Neil Levin, M.D., F.A.C.C. Based on an echocardiogram dated January 12, 2002, Dr. Levin attested in Part II of Ms. Chizar's Green Form that she suffered from moderate mitral regurgitation, a reduced ejection fraction in the range of 50% to 60%,[3] and pulmonary hypertension secondary to moderate or greater mitral

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2. (...continued)
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. Claimant later advised that Dr. Levin's representation of a reduced ejection fraction resulted from a "transcription error." Thus, the level of claimant's ejection fraction is not at issue.

regurgitation.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $574,011.[5]

In the report of claimant's echocardiogram, Dr. Levin stated that claimant had "[m]oderate [mitral regurgitation]." Dr. Levin, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Levin also measured claimant's pulmonary artery pressure as "56 mm Hg." Pulmonary hypertension secondary to moderate or greater mitral regurgitation is defined as peak systolic pulmonary artery pressure > 40 mm Hg measured by cardiac catheterization or > 45 mm Hg measured by Doppler Echocardiography, at rest, utilizing standard procedures assuming a right atrial pressure of 10 mm Hg. See id. § IV.B.2.c.(2)(b)I).

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4. Dr. Levin also attested that claimant suffered from New York Heart Association Functional Class II symptoms. This condition, however, is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Pulmonary hypertension secondary to moderate or greater mitral regurgitation is one of the complicating factors needed to qualify for a Level II claim.

In July, 2003, the Trust forwarded the claim for review by Kevin S. Wei, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Wei concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. In support of this conclusion, Dr. Wei explained that the "[p]lanimetry of the [mitral regurgitant] jet included low-flow signals that resulted in overestimation of jet area. Nyquist limit was set too low resulting in overestimation of color jet area." Dr. Wei also concluded that there was no reasonable medical basis for Dr. Levin's finding of pulmonary hypertension secondary to moderate or greater mitral regurgitation because the "[p]atient has only mild [mitral regurgitation]."

Based on the auditing cardiologist's diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Chizar's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, claimant submitted a letter from Dr. Levin wherein he stated, in pertinent part, that:

> Although the echo technician may have planimetered the [mitral regurgitant] jet in a fashion which somewhat overestimated the

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Chizar's claim.

> degree of mitral regurgitation (35%), I took that into account in assessing the degree of [mitral regurgitation]. I confirm my original finding of moderate mitral regurgitation. The color jet area is approximately 25%. There is also evidence for this degree of [mitral regurgitation] in the parasternal long axis view.

The Trust then issued a final post-audit determination, again denying Ms. Chizar's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Chizar's claim should be paid. On January 29, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3228 (Jan. 29, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on April 22, 2004. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[7] to review claims after the Trust and

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7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two (continued...)

claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issues presented for resolution of this claim are whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's findings that she had moderate mitral regurgitation and pulmonary hypertension secondary to moderate or greater mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Chizar resubmits the letter from Dr. Levin that she originally provided with her contest. Claimant also submits a letter from Allen L. Dollar,

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7. (...continued)
outstanding experts who take opposite positions" is proper. Id.

M.D., F.A.C.P., F.A.C.C. Dr. Dollar reviewed claimant's echocardiogram and concluded that Ms. Chizar had moderate mitral regurgitation. Dr. Dollar stated, in pertinent part, that:

> In the [parasternal long-axis ("PLAX")] view, the Nyquist limit was set at 57cm/s, which is a quite reasonable setting. Although the [mitral regurgitant] jet is never planimetered on the video in the PLAX view, the [mitral regurgitant] jet is quite impressive and clearly occupies more than 20% of the left atrial (LA) area.
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> Excellent examples of [mitral regurgitation] seen in the PLAX view can be seen at frames 0078.24 and 0080.13. I have visually estimated the [mitral regurgitation] in those frames at 35-40% of the LA area. There can be no question that these frames, at a minimum, show more than 20% of the LA area occupied by a very real high-velocity mosaic [mitral regurgitant] Doppler color jet measured using an appropriate Nyquist limit.

(Emphasis omitted.)

In response, the Trust argues that even claimant's attesting physician acknowledged that "the echo technician had over planimetered the [mitral regurgitant] jet." The Trust also asserts that a practice such as overtracing the RJA is indicative of an opinion beyond the bounds of medical reason. See PTO No. 2640 at 22, 26 (Nov. 14, 2002).[8]

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no

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8. Although the Trust also argues that Dr. Dollar's letter should not be considered because it was submitted beyond the end of the contest period, the Special Master, by letter dated December 8, 2004, accepted Dr. Dollar's letter and provided the Trust with an opportunity to respond. The Trust, however, did not submit a response to Dr. Dollar's letter.

reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Abramson determined that:

> In reviewing this transthoracic echocardiogram, my visual estimate is that there is only mild mitral regurgitation in both the parasternal views and apical views. The two specific frames that Dr. Dollar cites from the parasternal long axis view also demonstrate mild [mitral regurgitation]. In many views, the sonographer angled the transducer to maximize the size of the [mitral regurgitant] jet, which also truncated the size of the left atrium. This makes the RJA/LAA ratio appear larger than it truly is. I measured a left atrial area of 21.5 cm^2 in an 'on-axis' 4-chamber view (without color flow imaging), which represents the true size of the left atrium. Most of the cardiac cycles demonstrating the [mitral regurgitant] jet reduced the size of the left atrium. The sonographer clearly overtraced the mitral regurgitant jet. The Nyquist limit on the color flow imaging in the apical views for the mitral regurgitation is set at 49 cm/sec which is slightly lower than the usual Nyquist limit of 50 to 70 cm/sec. I doubt that this makes a significant difference in the size of the jet.
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> I measured the mitral regurgitant jet and the left atrial area (in the same frame) in five representative cardiac cycles. I tried to avoid measuring the cardiac cycles in which the left atrium size was significantly foreshortened. My measurements for mitral regurgitant jet area/left atrial area are $2.2cm^2/13.7\ cm^2$, $2.9cm^2/16.2\ cm^2$, $3.1cm^2/17.8\ cm^2$, $2.4cm^2/14.4\ cm^2$ and $2.3cm^2/17.4\ cm^2$. These ratios are 16%, 18%, 17%, 17%, and 13%, all of which are less than 20%, and are consistent with mild mitral regurgitation.

Dr. Abramson also determined that claimant had pulmonary hypertension but that there was no reasonable medical basis for

the attesting physician's finding of pulmonary hypertension secondary to moderate or greater mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation.

In response to the Technical Advisor Report, claimant contends that there is a reasonable medical basis for her attesting physician's finding of moderate mitral regurgitation "[b]ased on the re-measurement of Ms. Chizar's echocardiogram by Dr. Levin and the specific cited frames of the mitral regurgitation by Dr. Dollar." Ms. Chizar also argues that Dr. Abramson failed to measure these specific frames, relying instead on mere visual estimation when measuring was more appropriate. In addition, claimant asserts that Dr. Abramson failed to explain why her pulmonary hypertension was unrelated to her mitral regurgitation.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. We are not persuaded that the letters from claimant's attesting physician and Dr. Dollar provide a reasonable medical basis for Ms. Chizar's claim. Both Dr. Wei and Dr. Abramson reviewed claimant's echocardiogram and determined that it demonstrated only mild mitral regurgitation. Specifically, Dr. Abramson measured five representative cardiac cycles and noted that each ratio was "less than 20%." Dr. Abramson also reviewed the two frames identified by Dr. Dollar and concluded that they also represented only mild

mitral regurgitation.[9] Given the express findings of Dr. Wei and Dr. Abramson, the opinions of Dr. Levin and Dr. Dollar cannot provide a reasonable medical basis for Dr. Levin's representation.

Moreover, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26. During audit, Dr. Wei concluded that "[p]lanimetry of the [mitral regurgitant] jet included low-flow signals that resulted in overestimation of jet area. Nyquist limit was set too low resulting in overestimation of color jet area." Dr. Abramson also determined that "[i]n many views, the sonographer angled the transducer to maximize the size of the [mitral regurgitant] jet, which also truncated the size of

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9. In any event, as previously explained, the Settlement Agreement requires that mitral regurgitation be measured in an apical view, rather than parasternal long-axis view, which Dr. Dollar relied on for his measurements. See Settlement Agreement § I.22.

the left atrium. This makes the RJA/LAA ratio appear larger than it truly is.... The sonographer clearly overtraced the mitral regurgitant jet." Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.[10]

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation and pulmonary hypertension secondary to moderate or greater mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Chizar's claim for Matrix Benefits.

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10. As there is no reasonable medical basis for the attesting physician's finding that claimant suffered from moderate mitral regurgitation, there also cannot be a reasonable medical basis for the attesting physician's finding that claimant suffered from pulmonary hypertension secondary to moderate or greater mitral regurgitation.